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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/509,734	06/14/2000	SILVIU ITESCU	31856-PCT	2918
21003	7590	05/11/2004	EXAMINER	
BAKER & BOTTS 30 ROCKEFELLER PLAZA NEW YORK, NY 10112			SAUNDERS, DAVID A	
			ART UNIT	PAPER NUMBER
			1644	

DATE MAILED: 05/11/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/509,734

Applicant(s)

ITESCU, SILVIU

Examiner

David A Saunders, PhD

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 18 February 2004.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-19 is/are pending in the application.
- 4a) Of the above claim(s) 8-18 is/are withdrawn from consideration.
- 5) ☒ Claim(s) 1-7 is/are allowed.
- 6) ☒ Claim(s) 19 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

Claims 1-19 are pending.

Claims 1-7 and 19 are under examination.

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 2/18/04 has been entered.

The following typographical error has been noted in the office action of 8/13/03:

At page 3, line 13 "ercadth" should read as – breadth--.

The following 112 rejections of record are maintained:

Claim 19 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 19 is indefinite by reciting "a panel of control B lymphocytes" since one does not know what factors/variables these "control" ⁱⁿ for the methods.

Claim 19 is rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter, which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. Claim 19 contains new matter because recitation of merely "a panel of control B lymphocytes" is overly broad in comparison to "B

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lymphocytes obtained from a panel of control individuals representative of the most frequently encountered HLA class I and class II antigen in the general population" (see page 10, lines 15-17 and lines 30-31; see page 28, lines 17-19). It is also new matter for applicant to test only against a B-cell panel and not against both B and T panels.

Claim 19 is rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claim(s) contains subject matter, which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention. Claim 19 is not enabled because, from applicant's own disclosure, it appears that two control panels of B- and of T- lymphocytes are needed and that one determines DR (class II) reactivity by virtue of obtaining a ratio of reactivity against B-versus T- lymphocytes. See page 10, lines 22-23; page 11, lines 13-17; page 29 lines 7-18.

The above 112 rejections were not addressed by applicant in the submission of 2/18/04.

Due to applicant's amendment of claim 19, the prior art rejections over Itsecu et al have been modified as follows.

Claim 19 is rejected under 35 U.S.C. 102(a) as being anticipated by Itsecu et al (circulation, 98, 786, 1998).

Claim 19 is rejected under 35 U.S.C. 102(b) as being anticipated by Itsecu et al (Journal Heart Lung Transplant., 16, 78, 1997).

Both of the Itsecu et al references have been previously cited for disclosing the detection of IgG antibodies that react with members of a panel of cells. These

references teach testing for such antibodies in "pre-transplant" recipients. Applicant considered that the rejections of record have been overcome by reciting "post-transplant" in claim 19.

The examiner does not consider that mere recitation of "post transplant" in claim 19 overcomes, because in each of the references 23 of the patients may be reasonably considered as "post-transplant" recipients; this is because these 23 patients were "recipients of a second cardiac allograft"; see Itsecu et al (1998) at page 78 col. 1 under "methods". Itsecu et al (1997) refer to these 23 patients as those who had been recipients of "a first cardiac transplant" (line 6 of body of abstract). Thus, while the analysis presented by Itsecu et al can be considered per-transplant with respect to all of the patients (45 who had received a "first" transplant), the analysis may also be considered as "post-transplant" for those 23 patients who had been previously transplanted.

To overcome applicant must recite claim 19 with more precise language, so that it is clear that "detection of IgG anti-HLA-DR antibodies occurs "post-transplant" with respect to the particular tissue allograft that the "recipient is likely to reject" and not which respect to some other tissue allograft that the recipient has previously rejected.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to David Saunders whose telephone number is (571) 272-0849. The examiner can normally be reached on Monday to Thursday from 8 AM to 5:30 PM and on alternate Fridays.

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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christina Chan can be reached on (571) 272-0841. The fax phone number for the organization where this application or proceeding is assigned is 571-272³-1600.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Saunders/LR
May 3, 2004

David A. Saunders
DAVID SAUNDERS
PRIMARY EXAMINER
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